| Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office | Atty. Docket No. 34585-A-PCT-USA (070050.1739) | Serial No. 09/937,165 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)** | Applicant Fisher *et al.* | |
| | Filing Date September 21, 2001 | Group Not Yet Assigned |



## U.S. PATENT DOCUMENTS

| *Exam. Init. | | Document No. | Date | Name | Class | Subclass | Filing Date if Appropriate |
|---|---|---|---|---|---|---|---|
| GM | *30. | 5 4 6 4 7 5 8 | 11/7/95 | Gossen et al. | 435 | 69.6 | |
| | | | | | | | |
| | | | | | | | |



## FOREIGN PATENT DOCUMENT

| | | Document No. | Date | Country | Class | SubClass | Translator Yes | Translator No |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

## OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

| | | | |
|---|---|---|---|
| GM | 1. | | Blau, H., and Rossi, F.M.V. (1999). Tet B or not tet B: Advances in tetracycline-inducible gene expression. Proc. Natl. Acad. Sci. USA **96:**797-799. |
| | *2. | | Gopalkrishnan, R.V., Christiansen, K.A., Goldstein, N.I., DePinho, R.A., and Fisher, P.B. (1999). Use of the human EF-1alpha promoter for expression can significantly increase success in establishing stable cell lines with consistent expression: a study using the tetracycline-inducible system in human cancer cells. Nucleic Acids Res. **27:**4775-4782. |
| | 3. | | Bieschke, E.E., Wheeler, J.C., and Tower, J. (1998). Doxycycline-induced transgene expression during Drosophilia development and aging. Mol. Gen. Genet. **258:**571-579. |
| | 4. | | Gallia, G.L., and Khalili, K. (1998). Evaluation of an autoregulatory tetracycline regulated system. Oncogene **16:**1879-1884. |
| | 5. | | Kang, D.C., Motwani, M., and Fisher, P.B. (1998). Role of the transcription factor AP-1 in melanoma differentiation (review). Int. J. Oncol. **13:**1117-1126. |
| | 6. | | Kringstein, A.M., Rossi, F.M., Hofmann, A., and Blau, H.M. (1998). Graded transcriptional response to different concentrations of a single trasactivator. Proc. Natl. Acad. Sci. USA **95:**13670-13675. |
| | 7. | | Rossi, F.M., Guicherit, O.M., Spicher, A., Kringstein, A.M., Fatyol, K., Blakely, B.T., and Blau, H.M. (1998). Tetracycline-regulatable factors with distinct dimerization domains allow reversible growth inhibition by pl6. Nat. Genet. **20:**389-393. |
| GM | 8. | | Bohl, D., Naffakh, N., and Heard, J.M. (1997). Long-term control of erythoropoietein secretion by doxycycline in mice transplanted with engineered primary myoblasts. Nat. Med. **3:**299-305. |

NY02:345454.1



Examiner Shin-Lin Chen Date Considered 9-2-04

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office | Atty. Docket No. 34585-A-PCT-USA (070050.1739) | Serial No. 09/937,165 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)** | Applicant Fisher *et al.* | |
| | Filing Date September 21, 2001 | Group Not Yet Assigned |



| | | | |
|---|---|---|---|
| GM | 9. | | Faiss, M., Zalubilova, J., Strnad, M., and Schmulling, T. (1997). Conditional transgenic expression of the ipt gene indicates a function for cytokinins in paracrine signaling in whole tobacco plants. Plant J. **12**:401-415. |
| | 10. | | Fussenegger, M., Moser, S., Mazur, X., and Bailey, J.E. (1997). Autoregulated multicistronic expression vectors provide one-step cloning of regulated product gene expression in mammalian cells. Biotechnol Prog. **13**:733-740. |
| | 11. | | Hoffmann, A., Villalba, M., Journot, L., and Spengler, D. (1997). A novel tetracycline-dependent expression vector with low basal expression and potent regulatory properties in various mammalian cell lines. Nucl. Acd. Res. **25**:1078-1079. |
| | 12. | | Holwell, T.A., Schweitzer, S.C., and Evans, R.M. (1997). Tetracycline regulated expression of vimentin in fibroblasts derived from vimentin null mice. J. Cell. Sci. **110**:1947-1957. |
| | 13. | | Jost, M., Kari, C., and Rodeck, U. (1997). An episomal vector for stable tetracycline-regulated gene expression. Nucleic Acids Res. **25**:3131-3134. |
| | 14. | | Thompson, A.J., and Myatt, S.C. (1997). Tetracycline-dependent activation of an upstream promoter reveals transcriptional interference between tandem genes within T-DNA in tomato. Plant Mol. Biol. **34**:687-692. |
| | 15. | | Hofmann, A., Nolan, G.P., and Blau, H.M. (1996). "Rapid retroviral delivery of tetracycline-inducible genes in a single autoregulatory cassette. Proc. Natl. Acad. Sci. USA **93**:5185-5190. |
| | 16. | | Jiang, H., Su, Z.Z., Lin, J.J., Goldstein, N.I., Young, C.S., and Fisher, P.B. (1996). The melanoma differentiation associated gene mda-7 suppresses cancer cell growth. Proc. Natl. Acad. Sci. USA **93**:9160-9165. |
| | 17. | | Liang, X., Hartikka, J., Sukhu, L., Manthorpe, M., and Hobart, P. (1996). Novel, high expressing and antibiotic-controlled plasmid vectors designed for use in gene therapy. Gene Ther. **3**:350-356. |
| | 18. | | Paulus, W., Baur, I., Boyce, F.M., Breakefield, X.O., and Reeves, S.A., (1996). Self-contained, tetracycline-regulated retroviral vector system for gene delivery to mammalian cells. J. Virol. **70**:62-67. |
| | 19. | | Schultze, N., Burki, Y., Lang, Y., Certa, U., and Bluethmann, H. (1996). Efficient control of gene expression by single step integration of the tetracycline system in transgenic mice. Nat. Biotechnol. **14**:499-503. |
| GM | *20. | | Shockett, P.E., and Schatz, D.G. (1996). Diverse strategies for tetracycline-regulated inducible gene expression. Proc. Natl. Acad. Sci. USA **93**:5173-5176. |







Examiner Shin-Lin Chen Date Considered 9-2-04

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office | Atty. Docket No. 34585-A-PCT-USA (070050.1739) | Serial No. 09/937,165 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use several sheets if necessary) | Applicant Fisher *et al.* | |
| | Filing Date September 21, 2001 | Group Not Yet Assigned |




| | | | |
|---|---|---|---|
| SM | 21. | | Ackland-Berglund, C.E., and Leib, D.A. (1995). The efficacy of tetracycline-controlled gene expression is influenced by cell type. BioTechniques **18:**196-200. |
| | 22. | | Baron, U., Ferundlieb, S., Gossen, M., and Bujard, H. (1995). Co-regulation of two gene activities by tetracycline via a bidirectional promoter. Nucleic Acids Res. **23:**3605-3606. |
| | 23. | | Dhawan, J., Rando, T.A., Elson, S.L., Bujard, H., and Blau, H.M. (1995). Tetracycline-regulated gene expression following direct gene transfer into mouse skeletal muscle. Somat. Cell. Mol. Genet. **21:**233-240. |
| | 24. | | Efrat, S., Fusco-DeMane, D., Lemberg, H., al Emran, O., and Wang, X. (1995). Conditional transformation of a pancreatic beta-cell line derived from transgenic mice expressing a tetracycline-regulated oncogene. Proc. Natl. Acad. Sci USA **92:**3576-3580. |
| | *25. | | Gossen, M., and Bujard, H. (1995). Efficacy of tetracycline-controlled gene expression. influenced by cell type: commentary. BioTechniques **19:**213-216. |
| | *26. | | Gossen, M., Freundlieb, S., Bender, G., Muller, G., Hillen, W., and Bujard, H. (1995). Transcriptional activation by tetracyclines in mammalian cells. Science **268:**1766-1769. |
| | 27. | | Hennighausen, L., Wall, R.J., Tillmann, U.M., and; Furth, P.A. (1995). Conditional gene expression in secretory tissues and skin of transgenic mice using the MMTV-LTR and the tetracycline responsive system. J. Cell. Biochem. **59:**463-472. |
| | 28. | | Miller, K., and Rizzino, A. (1995). The function of inducible promoter systems in F9 embryonal carcinoma cells. Exp. Cell Res. **218:**144-150. |
| | *29. | | Shockett, P., Difilippantonio, M., Hellman, N., and Schatz, D.G. (1995). A modified tetracycline-regulated inducible gene expression. Proc. Natl. Acad. Sci. USA **92:**6522-6566. |
| | 31. | | Fishman, G. I., Kaplan, M.L., and Buttrick, P.M. (1994). Tetracycline-regulated cardiac gene expression in vivo. J. Clin. Invest. **93:**1864-1868. |
| | 32. | | Furth, P.A., St. Onge, L., Boger, H., Gruss, P., Gossen, M., Kistner, A., Bujard, H., and Hennighausen, L. (1994). Temporal control of gene expression in transgenic mice by a tetracycline-responsive promoter. Proc. Natl. Acad. Sci USA **91:**9302-9306. |
| SM | *33. | | Gossen, M., Bonin, A.L., Freundlieb, S., and Bujard, H. (1994). Inducible gene expression systems for higher eukaryotic cells" Curr. Opin. Biotechnol. **5:**516-520. |




NY02:345454.1

Examiner Shin-Lin Chen Date Considered 9-2-04

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office | Atty. Docket No. 34585-A-PCT-USA (070050.1739) | Serial No. 09/937,165 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)** | Applicant Fisher *et al.* | |
| | Filing Date September 21, 2001 | Group Not Yet Assigned |




| | | | |
|---|---|---|---|
| | 34. | | Wakabayashi-Ito, N., and Nagata, S. (1994). Characterization of the regulatory elements in the promoter of the human elongation factor-1 alpha gene. J. Biol. Chem. **269**:29831-29837. |
| | 35. | | Weinmann, P., Gossen, M., Hillen, W., Bujard, H., and Gatz, C. (1994). A chimeric transactivator allows tetracycline-responsive gene expression in whole plants. Plant J. **5**:559-569. |
| | *36. | | Gossen, M., and Bujard, H. (1992). Tight control of gene expression in mammalian cells by tetracycline-responsive promoters. Proc. Natl. Acad. Sci. USA **89**:5547-5551. |
| | *37. | | Kappel C.A., Zhang S.X., Bieberich C.J., and Jay G. (1992). Regulating gene expression in transgenic animals. Curr. Opin. Biotechnol. **3**:548-553. |
| | 38. | | Li, M., Hantzopoulos, P.A., Banerjee, D., Zhao, S.C., Schweitzer, B.I., Gilboa, E., and Bertino, J.R. (1992). Comparison of the expression of a mutant dihydrofolate reductase under control of different internal promoters in retroviral vectors. Hum. Gene Ther. **3**:381-390. |
| | 39. | | McKnight, R.A., Shamay, A., Sankaran, L., Wall, R.J., and Hennighausen, L. (1992). Matrix-attachment regions can impart position-independent regulation of a tissue- specific gene in transgenic mice. Proc. Natl. Acad. Sci. USA **89**:6943-6947. |
| | 40. | | Hasegawa, T., Nakada, S., Nakajima, T., Oda, K., Kawata, M., Kimura, H., and Sekiya, S. (1990). Expression of various viral and cellular enhancer-promoters during differentiation of human embryonal carcinoma cells. Differentiation **42**:191-198. |
| | *41. | | Kim, D.W., Uetsuki, T., Kaziro, Y., Yamaguchi, N., and Sugano, S. (1990). Uses of the human elongation factor 1 alpha promoter as a versatile and efficient expression system. Gene **91**:217-223. |
| | *42. | | Pursel V.G., Bolt D.J., Miller K.F., Pinkert C.A., Hammer R.E., Palmiter R.D., and Brinster R.L. (1990). Expression and performance in transgenic pigs. J. Reprod. Fertil. Suppl. **40**:235-245. |
| | 43. | | Stief, A., Winter, D.M., Stratling, W.H., and Sippel, A.E. (1989). A nuclear DNA attachment element mediates elevated and position-independent gene activity. Nature **341**:343-345. |
| | 44. | | Sleigh, M. J. (1987). Differential regulation of viral and cellular genes in F9 mouse embryonal carcinoma cells. Nucleic Acids Res. **15**:9379-9395. |
| | 45. | | Gorman, C.M., Rigby, P.W., and Lane, D. P. (1985). Negative regulation of viral enhancers in undifferentiated embryonic stem cells. Cell **42**:519-526. |






Examiner Shin-Lin Chen Date Considered 9-2-04

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office | Atty. Docket No. 34585-A-PCT-USA (070050.1739) | Serial No. 09/937,165 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)** | Applicant Fisher *et al.* | |
| | Filing Date September 21, 2001 | Group Not Yet Assigned |



| | | | |
|---|---|---|---|
| | | | Palmiter R.D., Norstedt G., Gelinas R.E., Hammer R.E., and Brinster R.L. (1983). Metallothionein-human GH fusion genes stimulate growth of mice. Science **222**:809-814. |



NY02:345454.1

Examiner Shin-Lin Chen Date Considered 9-2-04

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.